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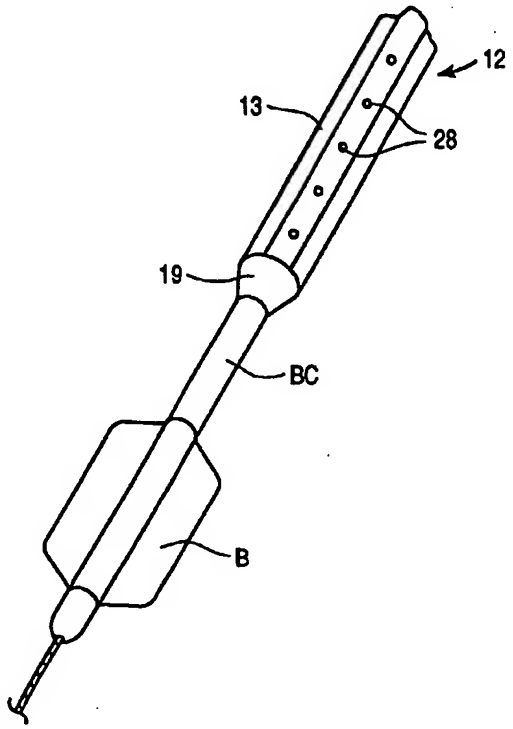
(54) Title: INFUSION SLEEVE CATHETER HAVING DISTAL DISTRIBUTION MANIFOLD

(57) Abstract

An infusion catheter (10) for use in combination with a balloon catheter comprises a shaft and a radially expansible infusion sleeve (12) attached to a distal end of the shaft. A manifold structure (14) connects a lumen within the shaft (16) to a plurality of lumens formed over the infusion sleeve (12). A balloon entry port (56) is provided at a proximal end of the infusion sleeve (12) to receive the balloon (B) of the balloon catheter (BC). The infusion catheter (10) and balloon catheter (BC) are introduced to a target location within a body lumen, typically a target site within a coronary artery, simultaneously. After use of the balloon catheter (BC) to treat the body lumen in a conventional manner, the expansible sleeve of the infusion catheter (10) may be advanced over the balloon (B), which is then inflated. An infuser is delivered through a delivery lumen in the shaft (16) to a plurality of infusion lumens (26) on the radially expanded sleeve while the balloon (B) remains inflated with the infuser exiting drug deliveryports (28) near the distal ends of the infusion lumens (26).



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INFUSION SLEEVE CATHETER HAVING DISTAL DISTRIBUTION MANIFOLD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to apparatus and methods for infusing fluids within body lumens. More particularly, the present invention relates to the use and construction of an infusion catheter which may be introduced to a body lumen over a balloon catheter.

Percutaneous translumenal angioplasty (PTA) procedures are widely used for treating stenotic atherosclerotic regions of a patient's vasculature to restore adequate blood flow. The catheter, having an expansible distal end usually in the form of an inflatable balloon, is positioned in the blood vessel at the stenotic site. The expansible end is expanded to dilate the vessel to restore adequate blood flow beyond the diseased region. While PTA has gained wide acceptance, it continues to be limited by two major problems: abrupt closure and restenosis.

The present invention is intended to address both problems and is particularly concerned with devices and methods for inhibiting restenosis by the localized delivery of fluid treatment agents. Such fluid treatment agents include anti-proliferative and anti-restenotic drugs intended specifically for post-angioplasty treatment, as well as anti-thrombotic, thrombolytic and fibrinolytic drugs useful for the acute treatment of atherosclerotic regions. The fluid treatment agents will include liquid drugs as well as solid drugs, including microcapsules and other controlled-release drug forms, present in a fluid dispersion. Restenosis refers to the re-narrowing of an artery after an initially successful angioplasty treatment. Restenosis afflicts approximately one in every three angioplasty patients and usually occurs within six months after the treatment. Patients suffering from

restenosis will require further treatment. Many different strategies have been proposed to reduce the restenosis rate, including mechanical (*e.g.*, prolonged balloon inflations during angioplasty, laser angioplasty, atherectomy, stenting and the like) and pharmacological, (*e.g.*, the administration of calcium antagonists, ACE inhibitors, fish oils, steroids, anti-metabolic drugs, and the like).

Pharmacologic treatment can be either achieved systemically or via localized drug delivery. While systemic delivery is particularly easy to administer to the patient, it suffers from a number of disadvantages, primarily the need to provide higher total dosages, but also including the possibility of systemic toxicity and a lack of site specificity. The localized delivery of fluid and dispersed drugs, in contrast, limits the total drug dosage required, and provides site-specific activity where the drug has a much higher local concentration than is possible with systemic delivery, particularly when delivered intramurally.

A variety of specialized catheters have been developed to deliver drugs to a vascular treatment site following angioplasty or other interventional procedures. Most such drug delivery catheters are balloon angioplasty catheters which have been modified to release drugs in some manner from the balloon portion of the catheter. The need to provide such a dual function, however, necessarily leads to compromises in the design of both the balloon and drug delivery aspects of the catheter. In order to avoid such compromises, other "dedicated" drug delivery catheters have been designed for separate delivery to the treatment site following the initial interventional procedure. The use of separate catheters, however, has certain disadvantages. First, the need to exchange the drug delivery catheter for the primary interventional catheter takes time, thus delaying the initiation of the drug treatment protocol. The need to exchange catheters also complicates and prolongs the procedure, increasing the time and cost to the patient. Additionally, many prior drug delivery catheters have been somewhat complex and costly, further increasing the cost of

the procedure, have had limited effectiveness, and/or have required long infusion times (up to 30 minutes). It would thus be desirable to provide improved drug delivery catheters which overcome some or all of these problems.

An improved catheter and method for delivering treatment agents to an angioplasty treatment site is described is U.S. Patent No. 5,336,178. Catheters employing the teachings of the patent have been developed under the tradename Kaplan-Simpson InfusaSleeve™ by LocalMed, Inc., Palo Alto, California. These devices are sleeve catheters having a plurality of drug infusion lumens formed over their entire lengths. A distal portion of the catheter is radially expansible and may be positioned over the balloon of a balloon catheter in order to engage drug delivery ports against the vessel wall by inflation of the balloon. Following angioplasty with a conventional angioplasty catheter, the drug infusion lumens of the sleeve catheter are aligned over the balloon of the same angioplasty catheter. The balloon is then used to expand the infusion lumens at the treatment site, and drug is introduced through the infusion lumens.

While representing a significant improvement over other drug delivery catheters, such sleeve infusion catheters have certain disadvantages. In particular, the presence of the coaxial sleeve over the balloon catheter with infusion lumens over the entire length increases the effective profile of the combined devices. This increase in cross-sectional area can present problems when the combined devices are introduced through a lumen of a conventional 8F guiding catheter (the most commonly used size) used to introduce the balloon and drug delivery catheters to the coronary arteries. In addition to "guiding" the angioplasty and infusion sleeve catheters, the lumen of the guiding catheter is used for delivering contrast medium to the coronary arteries (opacification) and measuring blood pressure through the contrast medium and blood in the lumen (transduction). In order to achieve adequate opacification and transduction with guiding catheters having a limited cross-sectional area within the guiding catheter of the lumen (*e.g.*, 8F guiding

catheters), it is necessary to minimize the cross-sectional area occupied by the combination of the angioplasty balloon catheter and the infusion sleeve catheter. The ability to limit the cross-sectional area of the infusion sleeve catheter, however, is limited by the need to accommodate passage of the balloon catheter and to maximize the cross-sectional areas of the drug infusion lumens. Drug infusion lumens having larger cross-sectional areas are desirable in order to minimize pressure drop and maximize fluid flow rates through the lumens for a given proximal infusion pressure.

For these reasons, it would be desirable to provide improved fluid infusion sleeve catheters of the type employed in combination with balloon catheters. It would be particularly desirable to provide improved infusion sleeve catheters which can reduce the total cross-sectional area occupied by the combination of the infusion sleeve and balloon catheters within a guiding catheter. Such reduction in cross-sectional area, however, should be achieved without substantial loss of internal cross-sectional area of the drug infusion lumen(s). That is, the improved infusion sleeve catheter should avoid any increase in pressure drop of the infusion fluid over the length of the catheter for a given infusion flow rate. Catheters of the present invention should further be manufacturable at relatively low cost and should optionally address at least some of the objectives and problems identified above.

2. Description of the Background Art

U.S. Patent No. 5,336,178 is described above. U.S. Patent No. 5,254,089 describes a drug delivery catheter having a plurality of drug infusion lumens formed integrally within an inflatable balloon. The infusion lumens are connected to a fluid delivery lumen in the catheter shaft.

The present application is related to the subject matter of commonly assigned, copending application serial numbers U.S. Serial No. 08/222,143, U.S. Serial No. 08/241,428, 08/221,613 and 08/305,250.

SUMMARY OF THE INVENTION

The present invention provides devices and methods for the delivery of therapeutic and other fluids to a target site within a body lumen. While the methods and devices will be particularly useful for the intravascular delivery of anti-restenotic, anti-proliferative, thrombolytic, fibrinolytic, and other agents useful in connection with angioplasty treatment in a patient's coronary vasculature, they will also find use for the delivery of a wide variety of other agents to other body lumens.

Apparatus according to the invention comprise an infusion sleeve catheter intended for use in combination with a balloon catheter. The infusion catheter comprises a shaft having a proximal end and a distal end, and a radially expansible infusion sleeve attached to the distal end of the shaft. A plurality of fluid infusion lumens are disposed over the infusion sleeve and connected to a fluid delivery lumen disposed within the shaft. A manifold structure is disposed between the fluid delivery lumen in the shaft and the fluid infusion lumens on the sleeve to provide for distribution of the fluid to said infusion lumens. The infusion sleeve will further include a central receptacle for receiving the balloon catheter, with an introduction port for the balloon located distally of the shaft, usually at or near the proximal end of the sleeve. In this way, the infusion sleeve can be mounted coaxially over the balloon catheter and be positioned near its distal end. The shaft of the infusion catheter, in contrast, would be disposed parallel to and not coaxially with the body of the balloon catheter in order to minimize the total cross-sectional area occupied by the combined shaft and body while maintaining sufficient cross-sectional area within the fluid delivery lumen for delivering fluids to the fluid infusion lumens.

According to the method of the present invention, a plurality of infusion lumens are positioned at a target site within a body lumen, such as a blood vessel. A balloon is inflated within the fluid infusion lumens to engage fluid delivery ports on the infusion lumens against an inner wall of

the body lumen. The balloon is formed separately from the fluid infusion lumens, thus permitting relative axial movement between the balloon and the fluid infusion lumens. Fluid is delivered through a fluid delivery lumen disposed in the body lumen, and distributed from the delivery lumen to the plurality of fluid infusion lumens at a location proximate the target site.

The apparatus and methods of the present invention are advantageous in a number of respects. First, the use of a single or reduced number of fluid delivery lumens to transfer fluid to a greater number of fluid infusion lumens can reduce the cross-sectional area occupied by the proximal portions of the infusion sleeve catheter. Such a decrease in cross-sectional area, however, can be achieved without a substantial increase in flow resistance (pressure drop at a given flow rate) within the delivery lumen(s). The decrease in cross-sectional area of the sleeve catheter should also be achieved with an improvement of pushability and trackability of the catheter. That is, the improved sleeve catheters should be able to be introduced together with and/or over conventional balloon angioplasty catheters to a target site within the vasculature and manipulated (i.e. advanced and retracted over the balloon catheter) at that site in a convenient manner. The catheters of the present invention are also simple to fabricate, thus reducing the cost and complexity of their manufacture.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of an infusion catheter constructed with the principles of the present invention.

Fig. 2 is a cross-sectional view taken along line 2-2 in Fig. 1.

Fig. 3 is a cross-sectional view taken long line 3-3 in Fig. 1.

Fig. 4 is a cross-sectional view taken long line 4 in Fig. 1.

Fig. 5 is a cross-sectional view taken along line 5-5 in Fig. 1.

Fig. 6 is a cross-sectional view taken along line 6-6 in Fig. 1.

Fig. 7 is a detailed view of the distal end of the catheter of Fig. 1 positioned over a balloon angioplasty catheter just proximal to an inflated balloon.

Fig. 8 is a detailed view of the distal end of the catheter of Fig. 1, similar to Fig. 7, shown with the balloon receptacle of the catheter positioned over the uninflated balloon of the balloon catheter.

Fig. 9 is a detailed view of the distal end of the catheter of Fig. 1, similar to Figs. 7 and 8, shown with the balloon receptacle positioned over an inflated balloon on the balloon angioplasty catheter.

Fig. 9A is a cross-sectional view of an alternative configuration of the balloon receptacle portion of a catheter constructed in accordance with the principles of the present invention.

Fig. 9B is a view similar to Fig. 9A, except that the balloon receptacle portion is shown in its radially expanded configuration.

Fig. 10 illustrates the infusion catheter of Fig. 1 introduced together with the balloon angioplasty catheter through a guide catheter positioned in the patient's aorta leading to one of the coronary ostia.

Fig. 11 is a cross-sectional view taken along line 11-11 of Fig. 10 illustrating the relative positions of the balloon angioplasty catheter body and the shaft of the infusion catheter within the guiding catheter.

Fig. 12 shows the relative positioning of a balloon angioplasty catheter body and an infusion catheter shaft, where the infusion catheter shaft has an oblong cross-section.

Figs. 13-15 illustrate alternative constructions for the shaft of the infusion catheter of the present invention.

Fig. 16 illustrates an alternative junction between the shaft and manifold sections of a catheter of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides apparatus and methods for infusing therapeutic, diagnostic, and other fluid media to target sites within a patient body lumen, such as a blood vessel. The fluid media which may be delivered include liquids, *e.g.*, where the drug is itself in liquid form and may be combined with saline and other conventional carrier fluids, and dispersions, where the drug may be in solid form (optionally being incorporated in microcapsules or other controlled-release delivery systems, including liposomes and other vesicles) and is dispersed in a suitable liquid carrier. The procedures will be performed "intralumenally," by which it is meant that the procedures occur at a target site within a body lumen, usually being within the patient vasculature, more usually being within the arterial system, including the coronary arteries, the peripheral arteries, and the cerebral arteries. The methods and apparatus of the present invention will find their greatest use in introducing therapeutic fluid agents, such as anti-restenotic drugs, anti-thrombotic drugs, thrombolytic agents, fibrinolytic agents, anti-proliferative agents, and the like, to sites within the coronary vasculature, where an infusion catheter according to the present invention is introduced simultaneously with a balloon angioplasty catheter through a conventional guiding catheter. The methods and apparatus of the present invention, however, are not limited to use in the vascular system, and may also be advantageously employed in other body lumens, including the urethra (*e.g.*, to treat benign prostatic hypertrophy, prostatitis, and adenocarcinoma), the fallopian tubes (*e.g.*, to treat strictures), brain parenchyma (to treat Parkinson's disease), and the like. The methods and apparatus of the present invention are not limited to the delivery of conventional drugs, and may also be used to deliver genes, nucleic acids, DNA constructs, and the like, usually present in liposomes or other carriers, intended for gene therapy and other therapeutic approaches.

The "target site" within the body lumen will usually be diseased or suspected of being diseased. In the case of

vascular treatment, exemplary target sites will be stenotic regions where blood flow is restricted as a result of atheromic deposits or plaque. Diseased sites within other body lumens are well known and described in the medical literature.

The infusion catheters of the present invention will be used in combination with radially expansible catheters, such as balloon catheters, of the type intended to dilatate body lumens, such as blood vessels. For example, angioplasty devices and catheters suitable for use in the present invention are described in U.S. Patent Nos. 5,041,089; 4,762,129; 4,775,371; 4,323,071 and 4,292,974, the full disclosures of which are incorporated herein by reference. Suitable angioplasty catheters are available commercially from suppliers such as Advanced Cardiovascular Systems, Inc., Temecula, California; Cordis Corp., Miami, Florida; Boston Scientific Co., Inc., Natic, Massachusetts, and others.

The infusion catheters of the present invention will comprise a radially expansible sleeve member mounted on the distal end of a shaft having an infusion fluid delivery lumen therein. The infusion sleeve will have a central receptacle for receiving the balloon or other expansible device on the conventional catheter as well as a plurality of fluid infusion lumens disposed over its outer surface or within its walls. The sleeve will be radially expansible over a portion which includes fluid infusion ports which are thus able to release fluids supplied to the lumens when the balloon or other expansion device is expanded therein. The infusion sleeve will be sufficiently large to receive a desired size of balloon or other expansible catheter and to accommodate the fluid infusion lumens over its upper surface or within its walls. Radial expansibility can be provided in a number of ways. In the exemplary embodiments, the sleeve will be axially split in order to allow radial expansion. Such expansibility can also be provided by use of an elastic material, use of an expansible braid material, use of a folded compliant or non-compliant material which will unfold when a balloon is inflated therein, and the like. A number of

specific designs for providing expansible balloon receptacles are described in copending application Serial No. 08/401,541, the full disclosure which is incorporated herein by reference.

The radially expansible sleeve will have a length sufficient to extend over the entire length of the catheter balloon when expanded. Usually, the sleeve will have a length which is greater than that of the balloon in order to facilitate connection of the sleeve to the shaft, as described in more detail herein below. Thus, the length of the sleeve will usually be at least 2.5 cm, typically being from 2.5 cm to 50 cm, usually being from 5 cm to 25 cm. The diameter of the sleeve will be sufficiently small to pass from the guide catheter, through the coronary ostium, and into the coronary vasculature, typically being below 2 mm, usually being in the range from 1.5 mm to 2 mm.

The fluid infusion lumens will extend over at least a portion of the radially expansible portion of the sleeve, usually, extending over that portion which is radially expanded by the balloon catheter. To simplify construction, and in particular to position the transition between the sleeve and the shaft of the infusion catheter within the guiding catheter during use, the infusion lumens will typically extend over the entire length of the infusion sleeve, usually being at least 2.5 cm in length, typically having a length in the range between 2.5 cm to 50 cm, and most usually having a length in the range from 10 cm to 25 cm. The perfusion ports which are formed in the sleeve to release infusate from the infusion lumens will usually extend only over a distal portion of the sleeve, normally being disposed only over the radially expansive portion which lies over the balloon to be inflated.

The diameter of the shaft portion of the infusion catheter will be smaller than that of the radially expansible infusion sleeve, typically being below 1 mm, preferably being below 0.8 mm, and often being 0.7 mm or below. In a first specific embodiment, the shaft may be formed from a simple tubular member having sufficient axial and flexural strength to permit manipulation of the catheter within the body lumen.

Exemplary tubular structures include hypo tube and other metal tubes having circular or non-circular cross-sections, as described in more detail below. Alternatively, the shaft structure may comprise extruded polymeric tubes having one, two, or more lumens, where the tubes are reinforced with internal rods. Such structures are advantageous since the shafts can be configured to have variable flexibility by using tapered reinforcement rods. In particular, such rods can be tapered to be highly flexible near their distal ends, and in some cases can be extended into at least a proximal portion of the radially expansible sleeve structure in order to enhance the pushability of the entire catheter. The fluid delivery lumen in the shaft will typically have a cross sectional area in the range from 0.2 mm^2 to 0.5 mm^2, preferably from 0.25 mm^2 to 0.35 mm^2. The shaft will typically have a length in the range from 90 cm to 150 cm, preferably from 100 cm to 125 cm.

The radially expansible infusion sleeve may be composed of a wide variety of biologically compatible materials, typically being formed from natural or synthetic polymers, such as polyamide (nylon), polyvinyl chloride, polyurethanes, polyesters, polyethylenes, polytetrafluorolethylenes (PTFE's), and nylons. A preferred material for the sleeve is polyamide (nylon).

The infusion sleeves will usually be non-compliant, and may optionally be reinforced to maintain patency of the infusion lumens during use. Usually, the sleeve structures will be formed by conventional extrusion of the desired polymeric material, forming both the central receptacle and the infusion lumens simultaneously. Cross-sectional areas and geometries of the infusion lumens and central receptacle may be controlled precisely using precision tooling mounted in a high precision extruder. With four infusion lumens, each lumen will typically have cross-sectional areas in the range from 0.05 mm^2 to 0.15 mm^2, usually from 0.08 mm^2 to 0.12 mm^2, and total (combined) cross-sectional areas in the range from 0.2 mm^2 to 0.6 mm^2, usually from 0.32 mm^2 to 0.48 mm^2.

At least a portion of the infusion sleeve will be radially expansible. Typically, the sleeve will be formed as

Referring now to Figs. 1-6, an exemplary infusion catheter 10 constructed in accordance with the principles of the present invention will be described. The infusion catheter 10 comprises a radially expansible infusion sleeve 12, a radially expansible portion 13 within the sleeve 12, a manifold section 14, and a shaft 16. A hub 18 is attached to the proximal end of the shaft 16 and may be connected to a source of infusion fluid, such as a syringe, pump, or the like. An atraumatic tip 19 is secured to the distal end of the sleeve 12. Distal end 20 of the shaft is secured within a proximal tubular extension 22 of the manifold structure 14. As illustrated in Figs. 1-6, the shaft 16 is a metal hypo tube having a circular cross-sectional area. The length of the shaft will depend on the length of the other portions of the catheter 10, with the overall length of the catheter typically being about 90 to 150 cm for coronary applications introduced through the femoral artery, as described in more detail below.

The radially expansible infusion sleeve 12 comprises a central receptacle 14 (Figs. 2 and 3) and four infusion lumens 26. Infusion ports 28 are formed over the distal-most 2.5 to 10 cm of the expansible portion 13 of the sleeve 12. Usually, the expansible portion 13 of the sleeve is axially split along lines 32 (Fig. 2) to permit radial expansion, as illustrated in Fig. 9 described below. The distal ends of the lumens 26 will be sealed, typically by the tip 19. Other structures for providing radial expansibility are described above.

The manifold structure 14 comprises an outer sheath or tube 40 coaxially received over an inner tube 42. Annular lumen 44 directs infusate into the infusion lumens 26. The annular lumen 44 is connected to lumen 50 and shaft 16 (Fig. 6) by a crescent-shaped transition lumen region 52 (Fig. 5) which is formed near the balloon catheter entry port 56. The balloon entry port 56 opens into a catheter lumen 58, which in turn leads into the balloon receptacle 24, typically having a cross-sectional area in the range from 0.5 mm^2 to 2 mm^2, typically about 1.25 mm^2.

Referring now to Figs. 7-9, a balloon catheter BC having an inflatable balloon B may be introduced through entry port 56 so that the balloon B extends outward through the distal tip of the sleeve 12. The balloon may then be inflated and deflated while the infusion sleeve 12 remains retracted. After the balloon B is deflated, the sleeve 12 may be advanced distally over the balloon, as illustrated in Fig. 8. By then inflating the balloon, the expansible portion 13 of the sleeve 12 will be expanded, as illustrated in Fig. 9.

The infusion sleeve 12 may have an alternative cross-section, as illustrated in Figs. 9A and 9B. The sleeve 12' may be formed with lumens 26' formed within the wall of the catheter, rather than on the outer surface of the catheter as illustrated in Figs. 2 and 3. The wall thickness in these constructions will typically be slightly greater, usually being in the range from 0.2 mm to 0.4 mm. The wall will be axially split along lines 32' in order to allow expansion, as shown in Fig. 9B.

Infusion catheter 10 may be introduced through conventional guiding catheter GC to position the infusion sleeve 12 within a coronary artery in the patient's heart H, as illustrated in Fig. 10. Guiding catheter GC may be any conventional guiding catheter intended for insertion into the femoral artery F, then via the patient's aorta A around the aortic arch AA, to one coronary ostia O. Such guiding catheters are commercially available through a number of suppliers, including Medtronic, Minneapolis, Minnesota, available under the tradename Sherpa™. Specific guiding catheters are available for introducing catheters to either the left main or the right coronary arteries. Such guiding catheters are manufactured in different sizes, typically from 7F to 10F when used for coronary interventional procedures.

According to the method of the present invention, the balloon catheter BC is introduced through the balloon entry port 56, as described previously in connection with Figs. 7-9. The atraumatic tip 19 of the infusion sleeve 12 will be positioned proximally of the balloon, typically by a distance in the range from 25 cm to 35 cm. The combination of

the balloon catheter BC, and infusion catheter 10 will be introduced through the guiding catheter GC over a conventional guidewire GW until the balloon is positioned within the target site within the coronary artery. Preferably, the infusion sleeve 12 will remain positioned entirely within the guiding catheter GC while the balloon B of the balloon catheter BC is initially located at the target site. The balloon may then be expanded to treat other regions within the coronary vasculature in a conventional manner. After the angioplasty treatment is completed, the infusion sleeve 12 will be advanced distally over the balloon catheter BC until the radially expansible portion is properly positioned over the balloon. Such positioning can be confirmed by proper alignments of radiopaque markers on the infusion sleeve 12 (not shown) with markers on the balloon catheter, typically within the balloon itself. After the infusion sleeve is properly positioned, the balloon B on the balloon catheter BC will be inflated to engage the infusion ports 28 against the inner wall of coronary artery.

A desired infusate is then delivered through the hub 18 for desired treatment. Typically, the infusate will be delivered at a flow rate from 10 ml/min to 40 ml/min, preferably from 20 ml/min to 30 ml/min. Infusion proximal pressures will typically be in the range of 30 psi to 150 psi, preferably from 70 psi to 110 psi. Balloon inflation pressures during infusion will typically be in the range from 0.5 atm to 6 atm, preferably from 1 atm to 2 atm. Specific treatment pressures, times, and other conditions will depend on the nature of the infusate and condition being treated. Typically, treatment periods will not exceed 5 mins., usually not exceed 3 mins. in order not to occlude the blood vessel for a longer time than is tolerable to the patient. Treatment protocols can be extended, however, by repetitively administering the infusate, *i.e.*, deflating the balloon to re-establish coronary perfusion and then re-inflating the balloon and delivering infusate after a time sufficient to perfuse the distal coronary tissue. Such delivery steps can be repeated

two, three, or more times as necessary to achieve a desired effect.

A particular advantage of the catheter construction of the present invention is maximization of the internal lumen area remaining in the guiding catheter GC when angioplasty, fluid infusion, and any other catheters are in place. As described above, prior sleeve-type infusion catheters which have infusion lumens extending the entire distance from their proximal ends to their distal ends will generally present a relatively high profile within the guiding catheter. For conventional coronary guiding catheters, typically having an outer diameter of 8 F, the remaining cross-sectional area of the guiding catheter lumen can be insufficient to provide adequate transduction (pressure measurement) and opacification (contrast agent delivery). By providing a separate (non-coaxial) catheter shaft on the infusion catheter of the present invention, the total cross-sectional area remaining within the guiding catheter can be maximized. This situation is illustrated in Fig. 11, where the guiding catheter GC is shown within a section of the patient's aorta A. Shaft 16 of catheter 10 is positioned parallel to the body of balloon catheter BC, leaving substantial cross-sectional lumen area available for transduction and opacification within the lumen of guiding catheter GC.

A modification of the shaft 16 is shown as 16' in Fig. 12. Shaft 16' has an oblong (illustrated as ellipsoidal) cross-sectional shape, which increases the lumenal area available within the shaft 16' without substantially decreasing the remaining annular cross-sectional area within the lumen of the guiding catheter GC. In particular, the oblong configuration increases the lumenal area of shaft 16', while leaving clearance between the body of the balloon catheter BC and the shaft 16' so that they may be advanced jointly or moved relative to each other without jamming.

Alternative oblong shaft cross-sections are illustrated in Figs. 13-15. Shaft 70 comprises an oblong, usually ellipsoidal shaft formed from an extruded polymer. Column strength is provided by a separate rod element 72 which

extends the entire length from the proximal end of shaft 70 to its distal end. As illustrated, the shaft 72 floats within the lumen 74 of shaft 70. In some cases, it will be desired to place the shaft 70 under axial tension by axially compressing the rod 72 and fixing the compressed rod 72 at both the proximal and distal ends of the polymeric shaft 70. Conveniently, the rod 72 could be fixed within a proximal hub (equivalent to hub 18 in Fig. 1) and extend into the manifold section which is located distally of the shaft 70. It is particularly desirable if the rod element 72 can extend at least past the balloon catheter entry port formed in the manifold section, as described hereinafter. Rod 72 may be constructed similarly to a guidewire shaft, and may optionally be tapered in order to provide for higher transverse flexibility near the distal end of the shaft. Fig. 14 illustrates a shaft 80 where support rod 82 is contained within a separate lumen 84. Lumen 86 remains for fluid delivery. Shaft 90 includes an extrusion having a pair of fluid delivery lumens 92 and 94. Rod 96 is disposed within a third lumen 98. A variety of other shaft structures may be used within the principles of the present invention.

Fig. 16 illustrates a preferred proximal end transition of the rod element 72 in a manifold region 14' on a catheter constructed in accordance with the principles of the present invention. The rod element 72 is tapered to have an increasingly smaller diameter in the distal direction, *i.e.*, the direction toward manifold region 14'. Typically the rod will have a diameter from 0.3 mm to 0.6 mm over most of its proximal length, but will taper down over the distal-most 10 cm to 20 cm to a diameter from 0.2 mm to 0.4 mm to enhance distal flexibility. Preferably, at its distal end 80, the rod 72 is flattened into a "spatula-shaped" cross-section. The distal end 80 is fixed within the polymeric body of the manifold region 14' using appropriate heat-shrinking techniques. Positioning of the rod 72 past the balloon catheter entry port 56' is particularly advantageous since it strengthens the otherwise-weakened portion of the catheter

body at the opening which is necessary to provide the port 56'.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. An infusion catheter for use in combination with a balloon catheter, said infusion catheter comprising:

a shaft having a proximal end and a distal end, and a fluid delivery lumen in between;

a radially expansible infusion sleeve attached to the distal end of the shaft, said infusion sleeve having a central receptacle for receiving the balloon catheter and a plurality of fluid infusion lumens disposed over its surface; and

a manifold structure disposed between the shaft and the infusion sleeve for distributing fluid from the delivery lumen to the infusion lumens.

2. An infusion catheter as in claim 1, wherein the shaft comprises a flexible metal tube having a single axial lumen therethrough which comprises the fluid delivery lumen.

3. An infusion catheter as in claim 1, wherein the shaft comprises a polymeric tube having a reinforcing rod extending from the distal end to the proximal end.

4. An infusion catheter as in claim 3, wherein the reinforcing rod is fixed within the manifold structure.

5. An infusion catheter as in claim 4, wherein the reinforcing rod is tapered in the distal direction.

6. An infusion catheter as in claim 5, wherein the reinforcing rod is under axial compression and fixed at each end within the polymeric tube.

7. An infusion catheter as in claim 1, wherein the infusion sleeve comprises a tubular web which is axially split between adjacent infusion lumens to permit balloon expansion therein.

8. An infusion catheter as in claim 1, wherein the infusion lumens each include a plurality of infusion ports axially spaced-apart there along.

9. An infusion catheter as in claim 1, wherein the manifold structure includes an intermediate annular lumen formed over the proximal end of the balloon-receiving receptacle.

10. An infusion catheter as in claim 1, wherein the single fluid delivery lumen has a cross-sectional area in the range from 0.2 mm^2 to 0.5 mm^2.

11. An infusion catheter as in claim 10, wherein each fluid infusion lumen has a cross-sectional area in the range from 0.05 mm^2 to 0.15 mm^2.

12. An infusion catheter as in claim 11, wherein the central receptacle has a cross-sectional area in the range from 0.5 mm^2 to 2 mm^2.

13. An infusion catheter as in claim 1, wherein the infusion sleeve has from two to eight axial infusion lumens disposed over its surface or within its wall.

14. An infusion catheter for use in combination with a balloon catheter, said infusion catheter comprising:

a shaft structure including (a) a polymeric tube having a proximal end, a distal end, and at least one lumen extending therebetween, and (b) a reinforcing rod extending from the proximal end to the distal end of the tube;

a hub attached to the proximal end of the shaft and having a single fluid connection port which is fluidly coupled to the lumen in the shaft structure;

an extruded polymeric infusion sleeve attached to the distal end of the shaft structure, said infusion sleeve including a radially expansible distal portion which comprises

a central receptacle for receiving the balloon catheter and a plurality of fluid infusion lumens; and

an intermediate manifold structure which comprises a manifold lumen for receiving fluid from the lumen of the shaft structure and distributing fluid to the fluid infusion lumens of the infusion sleeve.

15. An infusion catheter as in claim 14, wherein the radially expansible portion of the infusion sleeve compromises a tubular web which is axially split between adjacent infusion lumens to permit balloon expansion therein.

16. An infusion catheter as in claim 14, wherein the infusion lumens each include a plurality of infusion ports axially spaced-apart there along.

17. An infusion catheter as in claim 14, wherein the single fluid delivery lumen has a cross-sectional area in the range from 0.2 mm^2 to 0.5 mm^2.

18. An infusion catheter as in claim 17, wherein each fluid infusion lumen has a cross-sectional area in the range from 0.05 mm^2 to 0.15 mm^2.

19. An infusion catheter as in claim 18, wherein the central receptacle has a cross-sectional area in the range from 0.5 mm^2 to 2 mm^2.

20. An infusion catheter as in claim 14, wherein the infusion sleeve has from two to eight axial infusion lumens disposed over its surface.

21. An infusion catheter as in claim 14, wherein the reinforcing rod is fixed at its proximal end to the hub and at its distal end within the manifold structure.

22. An infusion catheter as in claim 21, wherein the reinforcing rod is under axial compression.

23. An infusion catheter as in claim 14, where the reinforcing rod is tapered to have a reduced width in the distal direction.

24. An infusion catheter as in claim 14, wherein the polymeric tube of the shaft structure includes at least two lumens, with the reinforcement rod being disposed within a lumen other than the lumen which delivers fluid to the infusion sleeve.

25. A method for infusing a fluid from an external source to a target site in a body lumen, said method comprising:

positioning a plurality of fluid infusion lumens at said target location;

inflating a balloon within said fluid infusions lumens to engage fluid delivery ports on said fluid infusion lumens against an inner wall of the body lumen at the target location, wherein the balloon is formed separately from the fluid infusion lumens;

delivering the fluid through a fluid delivery lumen, while said delivery lumen is disposed in the body lumen, to the fluid infusion lumens; and

distributing fluid from the fluid delivery lumen to the fluid infusion lumens to a location proximate the target site.

26. A method as in claim 25, wherein the body lumen is a blood vessel and the fluid is selected from the group consisting of anti-restenotic drugs, anti-thrombotic drugs, thrombolytic agents, and fibrinolytic agents.

27. A method as in claim 25, wherein the balloon is inflated to a pressure in the range from 0.5 atm to 6 atm.

28. A method as in claim 27, wherein the fluid is delivered through the fluid delivery lumen at a pressure in the range from 30 psig to 150 psig and at a rate from 10 ml/min to 40 ml/min.

29. A method for infusing a fluid from an external source to a target site in a coronary artery, said method comprising;

positioning an infusion sleeve over a balloon catheter so that said sleeve lies proximal of the balloon in a retracted configuration;

introducing the balloon catheter to the coronary artery through a guiding catheter with said infusion sleeve in the retracted configuration;

positioning a balloon on the balloon catheter at the target site;

advancing a shaft attached to the infusion sleeve to position the sleeve over the balloon wherein the shaft lies adjacent to the balloon catheter within the guiding catheter;

inflating the balloon to radially expand the sleeve and engage a plurality of fluid infusion lumens against the arterial wall and infusing fluid through a single fluid delivery lumen in the shaft and into the fluid infusion lumens to distribute the fluid into the arterial wall through a plurality of infusion ports in each fluid infusion lumen.

30. A method as in claim 29, wherein the fluid is selected from the group consisting of anti-restenotic drugs, anti-thrombotic drugs, thrombolytic agents, and fibrinolytic agents.

31. A method as in claim 29, wherein the balloon is inflated to a pressure in the range from 0.5 atm to 6 atm.

32. A method as in claim 31, wherein the fluid is delivered through the fluid delivery lumen at a pressure in the range from 30 psig to 150 psig and at a rate from 10 ml/min to 40 ml/min.

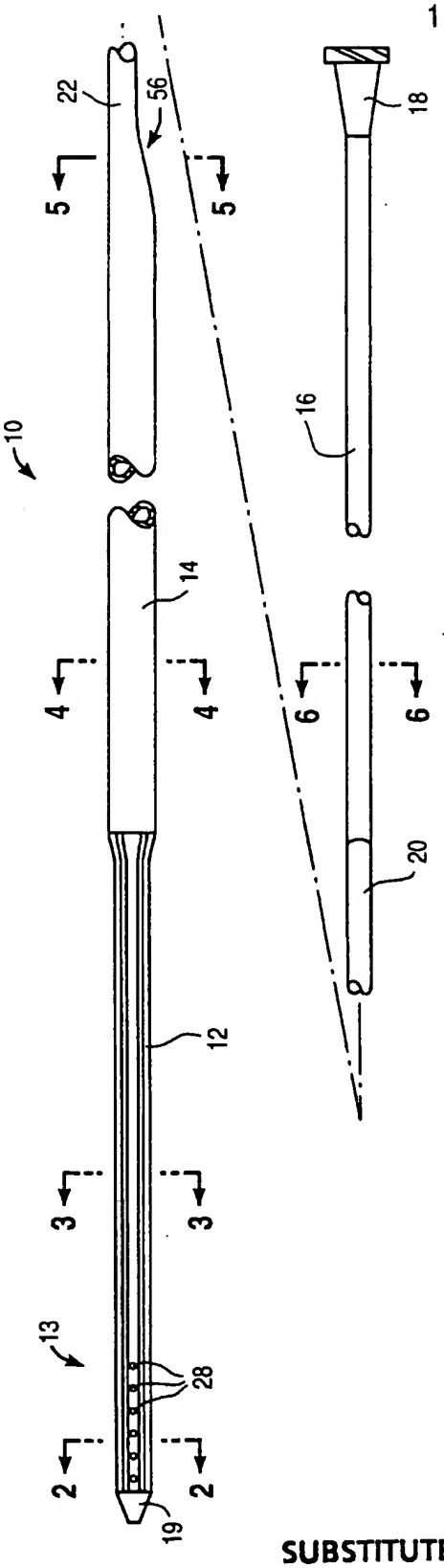

FIG. 1

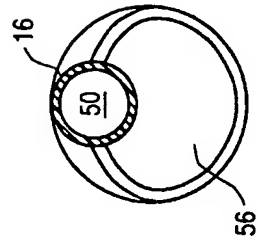

FIG. 6

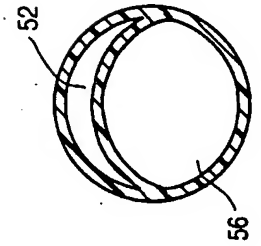

FIG. 5

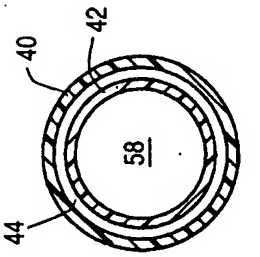

FIG. 4

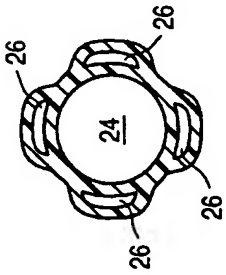

FIG. 3

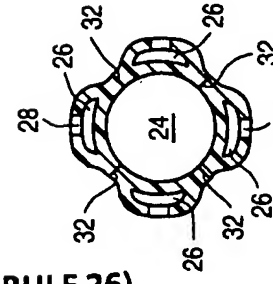

FIG. 2

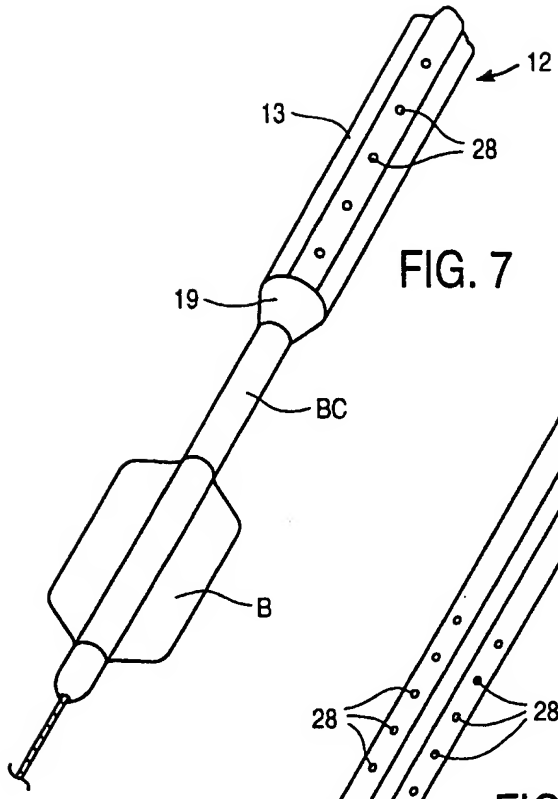

FIG. 7

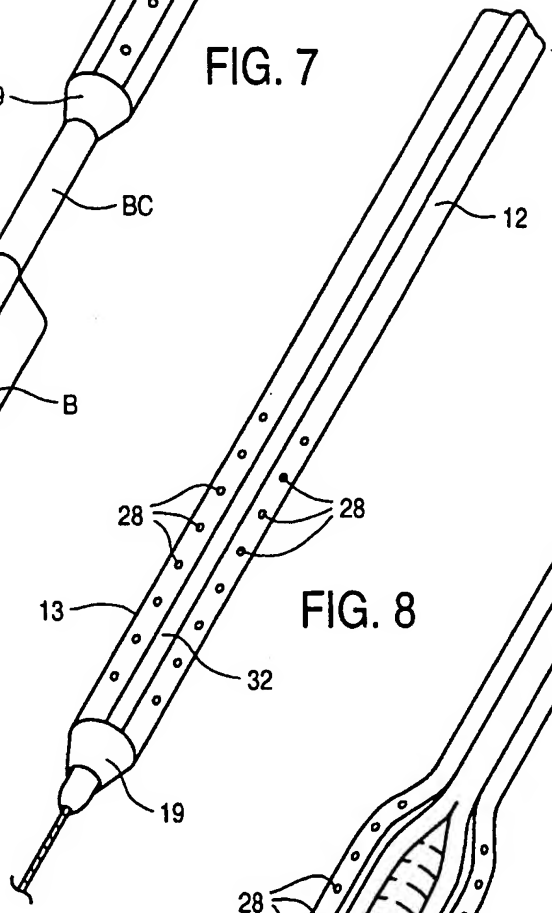

FIG. 8

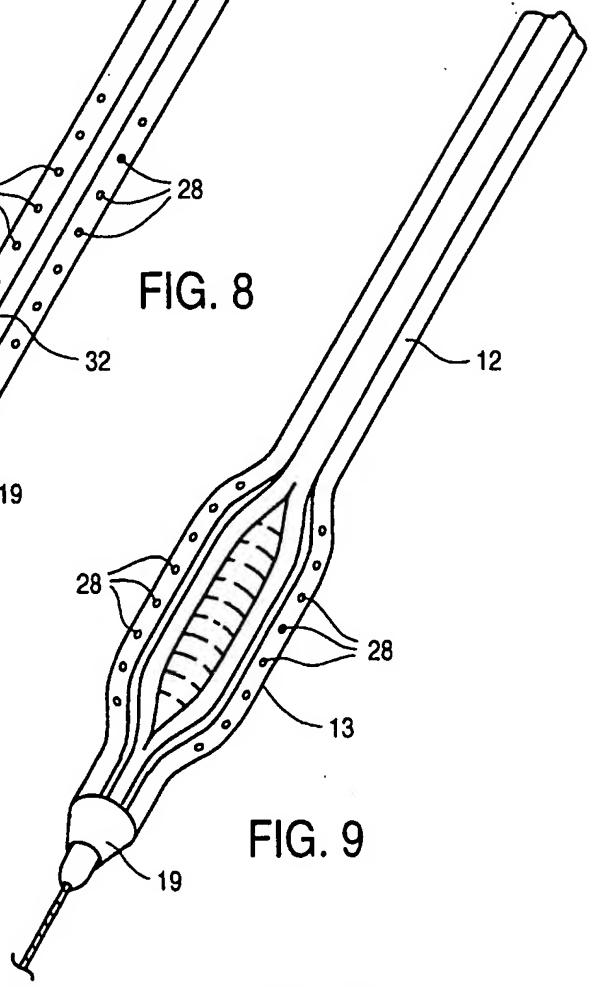

FIG. 9

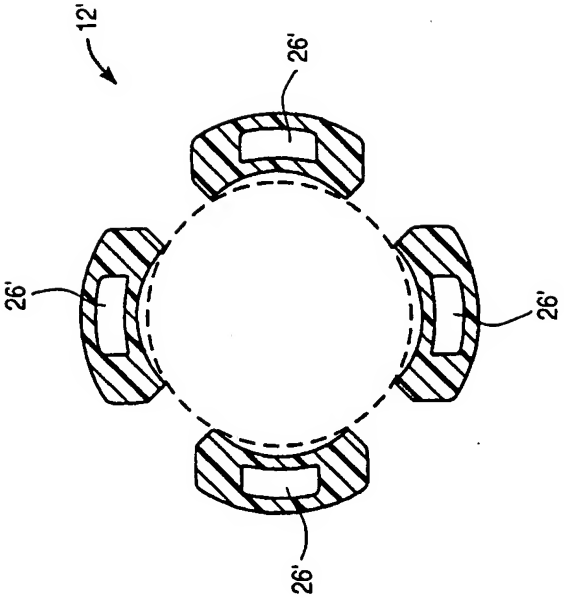

FIG. 9B

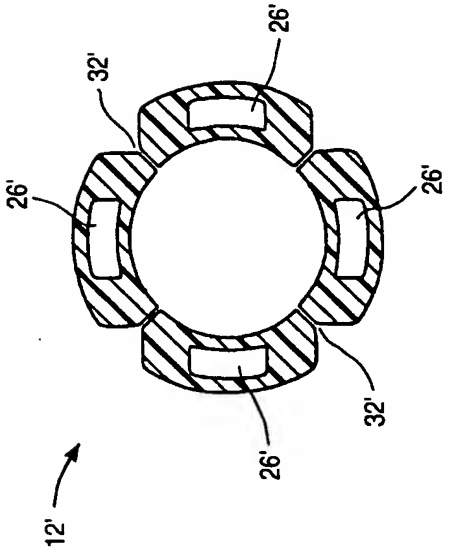

FIG. 9A

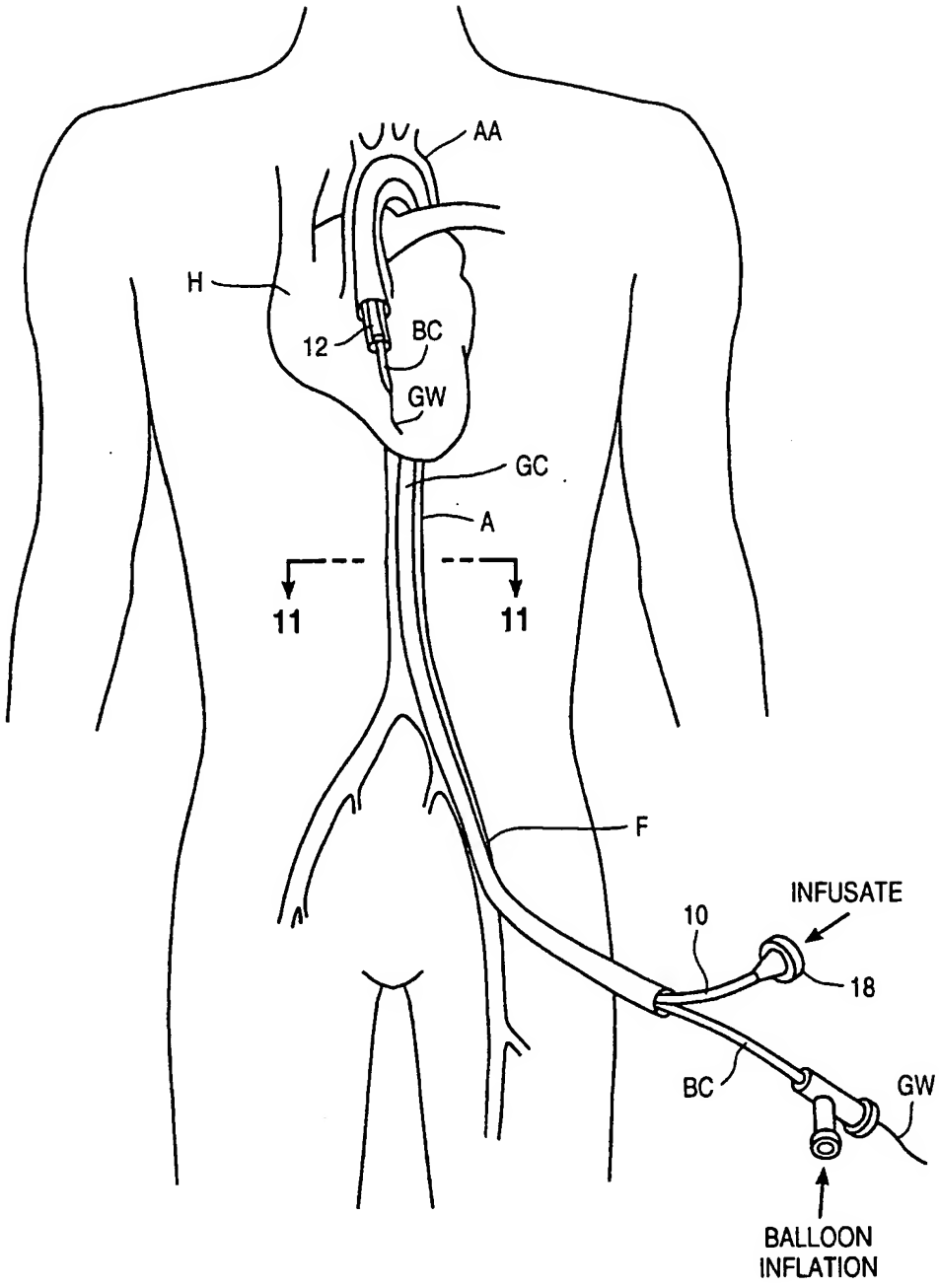

FIG. 10

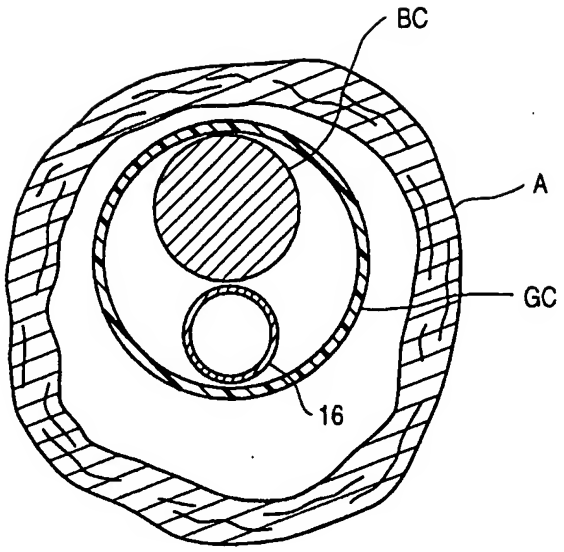

FIG. 11

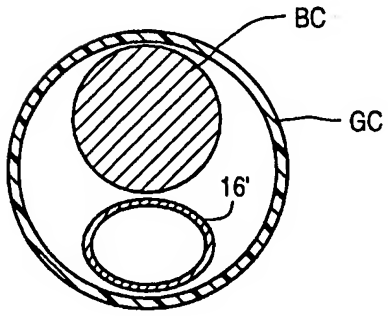

FIG. 12

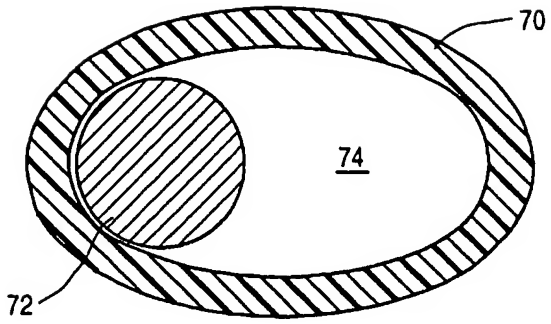

FIG. 13

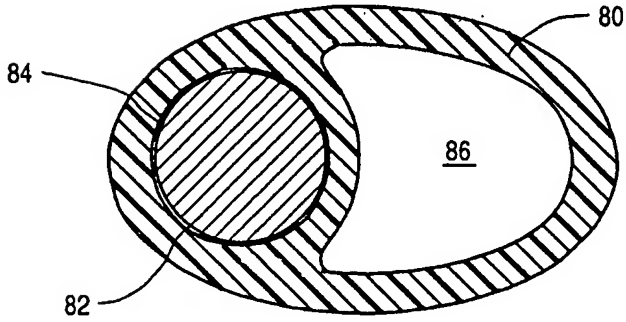

FIG. 14

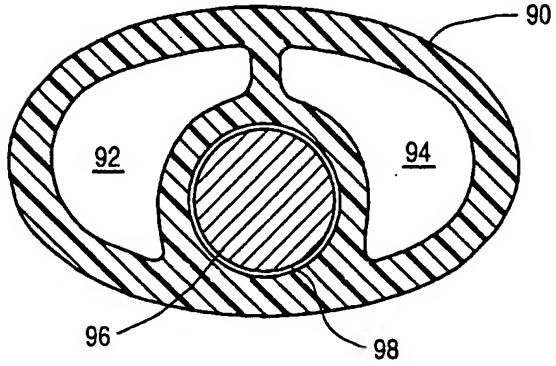

FIG. 15

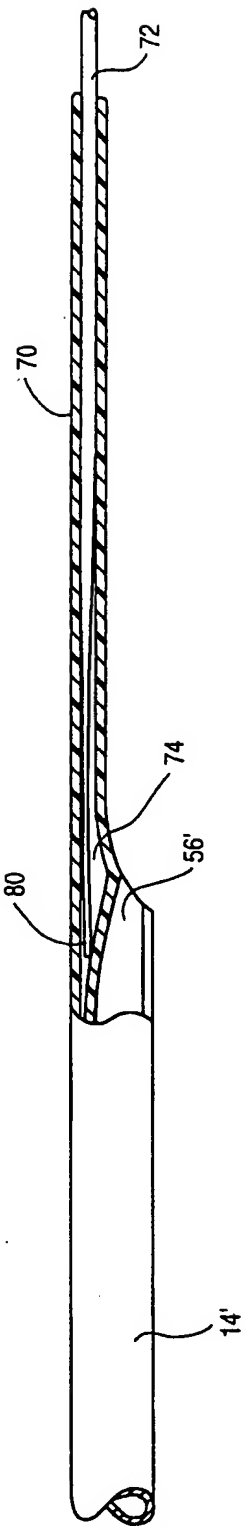

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/07489

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/53, 96; 606/194
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/53, 96; 606/194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,102,390 (CRITTENDEN ET AL.) 07 April 1992, see entire reference.	1-32
A	US, A, 5,242,451 (HARADA ET AL.) 07 September 1993, see entire reference.	1-32
A	US, A, 5,411,507 (HECKELE) 02 May 1995, see entire reference.	1-32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
11 AUGUST 1996	04 SEP 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer PERRY E. VAN OVER
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Form PCT/ISA/210 (second sheet)(July 1992)*